

November 24, 2003



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Isaac Jesus Rondon and Robert Charles Ladner

Application No.: 09/541,345

Group Art Unit: 1642

Filed: April 3, 2000

Examiner: K.A. Canella

Confirmation No.: 4862

Title: BINDING PEPTIDES FOR CARCINOEMBRYONIC ANTIGEN (CEA)

CERTIFICATE OF MAILING OR TRANSMISSION	
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Date	Signature
<i>Denise Caredio</i>	
Typed or printed name of person signing certificate	

REPLY UNDER 37 C.F.R. § 1.111

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Reply is being filed in response to the Office Action mailed from the Patent and Trademark Office on September 10, 2003 in the above-identified application. Reconsideration and further examination are requested. Remarks are set forth below with reference to the numbered paragraphs in the Office Action.

Image

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11/24/03

PATENT APPLICATION/1642
DOCKET NO. 3421.1005-000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Isaac Jesus Rondon and Robert Charles Ladner
Application No.: 09/541,345 Group Art Unit: 1642
File April 3, 2000 Examiner: K.A. Canella
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Denise Carideo

Signature

Denise Carideo

Typed or printed name of person signing certificate

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a Reply Under 37 C.F.R. § 1.111 for filing in the above-identified application.

[] Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a Small Entity Statement previously submitted.

[] A Small Entity Statement to establish small entity status under 37 C.F.R. 1.9 and 1.27 is enclosed.

The fee has been calculated as shown below:

(COL. 1)	(COL. 2)	(COL. 3)	(COL. 4)	(COL. 5)
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA
TOTAL	88	MINUS	* 88	0
INDEP	5	MINUS	** 5	0
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEP. CLAIM				

* not fewer than 20
** not fewer than 3

SMALL ENTITY		
	RATE	ADDIT. FEE
X	\$ 9	\$
X	\$43	\$
+	\$145	\$

TOTAL = \$ 0

OTHER THAN SMALL ENTITY		
	RATE	ADDIT. FEE
X	\$18	\$
X	\$86	\$
+	\$290	\$

TOTAL = \$ 0

Please charge Deposit Account No. 08-0380 for the following fees:

<input type="checkbox"/>	Petition for [] month Extension of Time	\$	_____
<input type="checkbox"/>	Amendment Fee	\$	_____
<input type="checkbox"/>	Other Fees:		
	_____	\$	_____
	_____	\$	_____
	TOTAL:	\$	<u>0</u>

A check is enclosed in payment of the following fees:

<input type="checkbox"/>	Petition for [] month Extension of Time	\$	_____
<input type="checkbox"/>	Amendment Fee	\$	_____
<input type="checkbox"/>	Other Fees:		
	_____	\$	_____
	_____	\$	_____
	TOTAL:	\$	<u>0</u>

☒ A general authorization is hereby granted to charge Deposit Account No. 08-0380 for any fees required under 37 C.F.R. 1.16 and 1.17 in order to maintain pendency of this application. A copy of this authorization is enclosed for accounting purposes.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie
Lisa M. Treannie
Registration No.: 41,368
Registration No.:
Telephone (978) 341-0036
Facsimile (978) 341-0136

Concord, Massachusetts 01742-9133

Dated: 11/24/03

Paragraph 3. Rejection of Claims 1-9, 23 and 24 under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 1-9, 23 and 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention (Office Action, page 2, lines 17-19). In the Examiner's opinion, the recitation of "CEA" is indefinite, as the prior art recognizes "CEA" as a family of proteins consisting of seven expressed proteins including NCA, BGP, CGM1, CGM2, CGM6 and CGM7 (Office Action, page 2, lines 20-23). In support of her position, the Examiner cites Hammarström, S., *Sem. Cancer Biol.* 9:67-81 (1999).

The second paragraph of 35 U.S.C. § 112 requires only that the claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity." In re Moore and Janoski, 169 USPQ 236, 238 (CCPA 1971). Further, the meaning of the claims is not analyzed in a vacuum, but in light of the teachings of the prior art and of the specification as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id. at 238.

Applicants' specification describes CEA as a particular protein and further describes homologous antigens to CEA. For example, Applicants' specification teaches:

CEA was as first described by Gold and Freedman, *J. Exp. Med.*, 121: 439, 1965, and has now been completely sequenced and characterized (see, Beauchemin et al., *Mol. Cell. Biol.*, 7:3221-30, 1987; WO 95/06067). CEA has a domain structure of N-A1-B1-A2-B2-A3-B3-GPI where GPI is a glycosphosphatidylinositol membrane anchor. A significant degree of sequence homology exists between the domains of CEA and other members of the immunoglobulin supergene family, and immunological cross-reactivity between CEA and as many as sixteen other homologous antigens, such as NCA and biliary glycoprotein-1 (BGP-1), has been reported.

Specification, page 2, lines 17-24.

Thus, although the prior art recognizes "CEA" both as a particular protein and as a family of proteins (i.e., the carcinoembryonic antigen (CEA) family, which includes seven expressed genes, i.e., CEA, NCA, BGP, CGM1, CGM2, CGM6, CGM7); see, e.g., Hammarström, page 68, paragraph bridging columns 1 and 2), it is clear from Applicants' specification that the recitation of "CEA" in Claims 1, 6, 8-10, 15, 16, 20, 23 and 24 refers to a particular protein and not a family of proteins.

The Examiner further states that "[i]t is unclear if applicant intends to claims [sic] proteins that bind only to CEA or to other CEA family members" (Office Action, page 2, lines 23-24, emphasis added). As discussed above, the recitation of "CEA" in the claims refers to a particular protein and not to a family of proteins. However, the subject claims are not to be construed as being limited to polypeptides that solely bind CEA. With the exception of Claim 8,

which specifies that the claimed polypeptide "binds to CEA but does not bind to NCA", the claims of the subject application require that the claimed polypeptide binds to the CEA protein, but the polypeptide may also bind to other proteins, including members of the CEA family of proteins. Reconsideration and withdrawal of the rejection are respectfully requested.

Paragraph 5. Provisional Rejection of Claims 1-9, 23 and 24 Under The Judicially Created Doctrine of Obviousness-Type Double Patenting

The Examiner has provisionally rejected Claims 1-9, 23 and 24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-13 of copending Application No. 09/825,517 (Attorney Docket No. 3421.1005-001). Office Action, page 3, lines 20-24. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the species encompassed by the claims of the '517 patent anticipate the claims of the subject application. Office Action, page 3, lines 22-24.

As stated by the Examiner, this is a provisional obviousness-type double patenting rejection because the claims deemed to be conflicting have not yet been patented. If this provisional rejection is the only rejection remaining after entry and consideration of this Amendment, Applicants respectfully request that the Examiner withdraw the rejection and permit the subject application to issue as a patent, in accordance with U.S. Patent Office procedure (see, M.P.E.P. § 804(I)(B), p. 800-19, Edition 8 (August, 2001)). Applicants will consider filing a terminal disclaimer and/or otherwise address any double patenting rejection that may be raised in U.S. Application No. 09/825,517 (Attorney Docket No. 3421.1005-001).

Information Disclosure Statements

Applicants thank the Examiner for considering and acknowledging her consideration of the information cited in the Information Disclosure Statements filed on October 30, 2000, October 7, 2002, and July 24, 2003. Applicants further filed an Supplemental Information Disclosure Statement on October 9, 2003. The Examiner is respectfully requested to consider the references cited therein and to provide acknowledgment of consideration of the information provided in the Supplemental Information Disclosure Statement in the next Office Communication.

CONCLUSION

In view of the above remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie
Lisa M. Treannie
Registration No.: 41,368
Telephone: (978) 341-0036
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